No. 92-303

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

ALBERT SLATER,
Petitioner,

v.

OPTICAL RADIATION CORPORATION,
Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Seventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act preempt state law damage claims for defective design, failure to warn, and breach of warranty against the manufacturer of an investigational medical device, under a provision that bars States from establishing device requirements that are "different from, or in addition to," a requirement under the MDA, where (1) Food and Drug Administration regulations allow preemption only if the FDA has established specific counterpart requirements concerning the device, and there are no such FDA requirements concerning the design or warnings for the device in question, and (2) the FDA has, by regulation, barred any manufacturer of an investigational device from obtaining the patient's release from liability?

TABLE OF CONTENTS

QUESTION PRESENTED i

TABLE OF AUTHORITIES iii

OPINIONS BELOW 1

JURISDICTION 1

STATUTORY PROVISION INVOLVED 2

REGULATORY PROVISIONS INVOLVED 3

STATEMENT OF THE CASE 4

REASONS FOR GRANTING THE WRIT 9

A. The Ruling of the Court of Appeals is Inconsistent With (1) Authoritative Regulations of the FDA, (2) Decisions of Other Federal and State Courts, and (3) This Court's Ruling in *Cipollone*. 9

B. The Court of Appeals Erred in Assuming That the MDA Preempts Damage Claims. 17

C. There is a Split in Authority Over the FDA's Savings Clause for Liability Actions Pertaining to Investigational Devices. 21

CONCLUSION 23

TABLE OF AUTHORITIES

Cases: **Page:**

Bejarano v. Int'l Playtex, Inc., 750 F. Supp. 443 (D. Idaho 1990) 13

Berger v. Personal Products, Inc., 797 P.2d 1148 (Wash. 1990) 20

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) 15

Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) 20

Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) 4, 15-17, 21, 22

Desmarais v. Dow Corning Corp., 712 F. Supp. 13 (D. Conn. 1989) 13

English v. General Electric Co., 496 U.S. 72 (1990) 23

Hillsborough County, Fla. v. Automated Medical Laboratories, Inc., 471 U.S. 707 (1985) 13, 15

Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn. 1989) 20

Krause v. Kimberly-Clark Corp., 749 F. Supp. 164 (W.D. Mich. 1990) 13

Lavetter v. Int'l Playtex, Inc., 706 F. Supp. 722 (D. Ariz. 1988) 13

Lindquist v. Tambrands, Inc., 721 F. Supp. 1058 (D. Minn. 1989) 20

Mitchell v. IOLAB Corp., 700 F. Supp. 877 (E.D. La. 1988) 7, 8, 21

Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989) 8, 10, 12, 15

National Women's Health Network, Inc. v. A.H. Robins Co., Inc., 545 F. Supp. 1177 (D. Mass. 1982) 13, 19

New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 795 (N.J. 1978) 14, 18, 20, 22

Red Lion Broadcasting Co. v. F.C.C., 395 U.S. 367 (1969) 14

Rinehart v. Int'l Playtex, Inc., 688 F. Supp. 475 (S.D. Ind. 1988) 13

Schneidewind v. ANR Pipeline Co., 485 U.S. 293 (1988) 9

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) 23

Smith v. Pingree, 651 F.2d 1021 (5th Cir. Unit B 1981) 13, 14

Wisconsin Public Intervenor v. Mortier, 111 S. Ct. 2476 (1991) 21

Statutes and Regulations:

Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et. seq.* 4

21 U.S.C. § 360j(e) 12

21 U.S.C. § 360j(g) 5, 12

21 U.S.C. § 360k 2, 23

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(*b*) 19, 20

28 U.S.C. § 1254(1) 1

28 U.S.C. § 1441(a) 5

21 C.F.R. § 50.20 ..... 3, 7, 8, 21-23

21 C.F.R. § 801.420(c) 13

21 C.F.R. § 801.430 ..... 10, 12

21 C.F.R. § 808.1 14

21 C.F.R. § 808.1(b) 6, 18

21 C.F.R. § 808.1(d) 3, 6, 11

21 C.F.R. § 808.1(d)( ) 17, 19

21 C.F.R. § 808.1(d)(3) 12

21 C.F.R. § 808.1(d)(6)(i) 12

21 C.F.R. § 808.1(d)(6)(ii) 12

21 C.F.R. § 808.20 20

21 C.F.R. § 808.25 20

21 C.F.R. § 812.3(n) 7

21 C.F.R. Part 813 ..... 5, 7, 10

21 C.F.R. § 813.3(g) 7

21 C.F.R. § 813.5(c)(4) 21

21 C.F.R. § 813.20 7

21 C.F.R. § 813.30 7

21 C.F.R. § 813.65 7

43 Fed. Reg. 18,661 (May 2, 1978) 11, 19

45 Fed. Reg. 67,321 (October 10, 1980) 15, 19

Ill. Rev. Stat., Ch. 26, § 2-314 6

Ili. Rev. Stat., Ch. 26, § 2-315 6

Legislative History:

H.R. Rep. No. 94-853, 94th Cong., 2d Sess. (1976) 18

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ALBERT SLATER,
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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit is reported at 961 F.2d 1330 (1992), and is reproduced in the appendix at 1a-8a. The decision of the United States District Court for the Northern District of Illinois is reported at 756 F. Supp. 370 (1991), and is reproduced in the appendix at 9a-16a.

JURISDICTION

The judgment of the court of appeals was entered on April 22, 1992. Petitioner filed a timely petition for rehearing and rehearing en banc on May 6, 1992, which was denied by the court of appeals on May 20, 1992 (17a). This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement--
>
> (A) is required by compelling

local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

REGULATORY PROVISIONS INVOLVED

21 C.F.R. § 50.20 provides in relevant part:

No informed consent [to the use by a patient of an investigatory medical device], whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

21 C.F.R. § 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the pur-

> pose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

STATEMENT OF THE CASE

The question in this case is whether, as the Seventh Circuit held prior to this Court's ruling in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, preempt all state law damage claims against manufacturers of investigational medical devices. We believe that the court of appeals erred because the statute's express preemption provision is narrowly drawn to apply only to situations where there is a counterpart federal regulation, and because the provision applies only to State and local rules or prohibitions, not damage claims. These conclusions are directly supported by regulations of the FDA, the federal agency specifically charged with enforcing the MDA.

Moreover, the decision below would leave injured patients without any remedy against the device manufacturer of any investigational device, regardless of the gravity of the injury or the theory of liability alleged, a result which is directly contradicted by another FDA regulation which specifically forbids investigational device manufacturers from disclaiming their liability. Review is also warranted because the lower courts are divided over the preemptive scope of the Medical Device Amendments and because the decision of the court of appeals is at odds with this Court's Supremacy Clause jurisprudence.

On July 19, 1984, petitioner Albert Slater underwent surgery for the removal of a cataract in his left eye at the Hinsdale Hospital in Hinsdale, Illinois. Amd. Compl. ¶ 7. At the same time, an anterior chamber intraocular lens ("IOL"), known as the Stableflex, was implanted in Mr. Slater's left eye. The purpose of an IOL is to replace the patient's natural lens that is, as a matter of course, destroyed in cataract surgery (3a). The Stableflex,

which was designed, manufactured, and sold by respondent Optical Radiation Corporation ("ORC"), was implanted in approximately 66,000 patients under procedures for the marketing of investigational medical devices (2a-3a). *See* 21 U.S.C. § 360j(g); 21 C.F.R. Part 813.

Over the next several years, petitioner developed glaucoma, and, as the court of appeals put it, "the vision in Slater's left eye deteriorated, he experienced continuous pain, the eye became infected, and eventually the implant had to be removed, leaving him with permanent damage to the eye (beyond the damage done by the cataract itself)" (3a). Petitioner began treatment for the glaucoma and his other eye problems, and in April 1987, his doctors determined that the Stableflex lens could be the cause of his pain and deteriorating vision. Amd. Compl. ¶ 13.

In June 1987, petitioner's Stableflex lens was removed by Dr. Leo Maguire of the Mayo Clinic. *Id.* ¶ 14. Dr. Maguire determined that the lens had "cocooned" in petitioner's eye and was extremely difficult to remove because of its "awkward design" (3a). On the day following petitioner's surgery, Dr. Maguire wrote to the Food and Drug Administration ("FDA"), reporting his finding that the Stableflex lens was poorly designed and urging that the device be taken off the market immediately. Amd. Compl. ¶ 15. At about that time, ORC removed the Stableflex from the market (4a).

On September 22, 1988, petitioner filed this action in Illinois state court, and respondent removed the case based on diversity of citizenship under 28 U.S.C. § 1441(a). Thereafter, petitioner filed an amended complaint alleging that ORC was negligent under the common law of Illinois because it had designed, manufactured, and distributed the Stableflex in a manner that was unsafe for implantation in the human eye. Amd. Compl. ¶¶ 17-19. In particular, Mr. Slater claimed that ORC had sold the Stableflex knowing that it was not properly tested and that it could cause damage to the human eye, that ORC had not adequately warned consumers of the lens' defects, and that ORC knew or should have known that the lens was improperly designed. *Id.* ¶ 18. Petitioner also sought relief under a strict liability theory -- that the Sta-

bleflex was unreasonably dangerous and defectively designed and that ORC failed to adequately warn users of its adverse effects on the eye -- and on the ground that ORC had breached the implied warranties of merchantability and of fitness for a particular purpose under the Illinois Uniform Commercial Code. *Id.* ¶¶ 20-26; *see* Ill. Rev. Stat., Ch. 26, §§ 2-314 and 2-315.

The district court granted ORC's motion to dismiss on the ground that Mr. Slater's claims were expressly preempted by the MDA (9a). The district court turned first to 21 U.S.C. § 360k(a), which provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The court then noted that state "court decision[s]" (14a), as well as statutes, ordinances, and regulations, may be preempted by the MDA to the extent that they fall within the scope of § 360k(a). *See* 21 C.F.R. § 808.1(b). The court acknowledged, however, that the FDA, which had promulgated regulations interpreting the MDA's preemption provision, did not intend to preempt all state and local law pertaining to devices, but only those "State or local requirements . . . whe[re] the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . ." *Id.* § 808.1(d).

Combining what it believed to be the relevant statutory and regulatory criteria, the district court concluded that the MDA "ex-

pressly preempts any state tort standard" that would impose upon medical device manufacturers any requirement different from, or in addition to, specific counterpart regulations or other specific requirements promulgated by the FDA (14a). The court found these "counterpart" requirements in the regulations for IOLs that the FDA had promulgated in 1977 that prescribe the steps that manufacturers must take to obtain an Investigational Device Exemption for an IOL. These regulations describe the types of information that IOL manufacturers must submit in order to market their devices on an investigational basis, without the normal full-scale approval by the FDA for safety and efficacy. 21 C.F.R. Part 813. The regulations require, among other things, an application explaining a plan for a clinical investigation on human subjects (*id.* § 813.20), evaluation by both a review committee and the FDA (*id.* §§ 813.20, .30), and monitoring of the clinical investigation (*id.* § 813.65).

None of these regulations require that IOLs -- investigational or otherwise -- meet any design or performance standards, nor do they require that IOLs bear specific warnings or meet certain labeling requirements. Nonetheless, the district court held that, because the FDA's regulations concern "safety and effectiveness" of IOLs, any damage award in this case would be "different from, or in addition to" the FDA's requirements (15a). Therefore, petitioner's claims were preempted by 21 U.S.C. § 360k(a)(16a).

The Seventh Circuit affirmed in an opinion written by Judge Richard A. Posner (1a). It began by noting that the district court's opinion was at odds with *Mitchell v. IOLAB Corp.*, 700 F. Supp. 877 (E.D. La. 1988). That case held that 21 C.F.R. § 50.20, which prohibits the sponsors (*i.e.*, the manufacturers, *see* 21 C.F.R. §§ 812.3(n), 813.3(g)) of investigational devices from including any "exculpatory language" in informed consents obtained from patients and from disclaiming any "liability for negligence," defeated any claim that the MDA preempts a design defect action against the manufacturer of an investigational IOL. *Mitchell*, 700 F. Supp. at 878-79.

The court of appeals dealt first with what it described as "the

plaintiff's real gripe" (4a) -- his claim that the Stableflex was defectively designed under Illinois common law. Because, Judge Posner explained, "[t]he FDA's regulations imposed no requirements concerning the design of intraocular lenses, ... the plaintiff argues, there is no preemption of state products liability law relating to design defects" (*id.*, *citing Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989)). The court rejected this theory because it thought that Congress did not expect the FDA to approve a specific design for an investigational device, and that the FDA's decision to grant investigational status to ORC's IOL "is a certification that the design is sufficiently safe and effective to allow experimental use on human beings" (5a). Thus, the court held, Mr. Slater's theory of recovery represented "a direct collision with federal policy" (*id.*), amounting to an additional requirement relating to the safety and effectiveness of the device within the meaning of the MDA's preemption provision.

Preemption is also appropriate, the court believed, because, if tort liability were imposed on the manufacturer, fewer experimental treatments would be available (6a). Moreover, because Mr. Slater was informed that his IOL was investigational, and he chose to undergo the operation, he assumed the risks of that operation (*id.*). For this reason as well -- petitioner's purportedly informed consent to implantation of the device -- the claim that ORC failed to give petitioner a warning that was adequate under Illinois common law also failed (7a).[1]

The court of appeals observed that the MDA does not preempt actions against physicians or hospitals for negligent implantation or contamination of an IOL as long as they do not relate to the "safety or effectiveness" of the lens (6a). In the court's view, this explained 21 C.F.R. § 50.20, the provision making it unlawful to release a manufacturer's liability concerning investigational devices. Rather than making clear that damage actions against investigational device manufacturers are not preempted, as *Mitchell* had held, 700 F. Supp. at 878-89, this

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[1] The court of appeals failed entirely to address whether petitioner's breach of implied warranty claims under the Illinois UCC were preempted (*see infra* at 16).

provision, according to the court of appeals, simply acknowledges the truism that state law claims not preempted by the MDA may go forward (7a), although the court did not identify which claims, if any, remained against a manufacturer of an investigational device.

REASONS FOR GRANTING THE WRIT

The lower federal courts are deeply split over the preemptive reach of the Medical Device Amendments and, in particular, what constitutes a State or local device "requirement" that is "different from, or in addition to" requirements imposed by federal law. 21 U.S.C. § 360k(a). Some courts have held, in reliance on FDA regulations, that MDA preemption is very narrow, occurring only where the FDA has promulgated, or the MDA itself contains, subject-specific, device-specific requirements *and* a State or locality has attempted to legislate or issue regulations in that precise area. Other courts, most notably the court of appeals here, have held that, even where the FDA has acted more generally, such as in its rules for the marketing of investigational devices, the MDA preempts *any* state law attempt, even through a common law tort claim, to protect an injured consumer.

A. The Ruling of the Court of Appeals is Inconsistent with (1) The Authoritative Regulations of the FDA, (2) Decisions of Other Federal and State Courts, and (3) This Court's Ruling in *Cipollone*.

Preemption is fundamentally a question of legislative intent, *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299 (1988), which means the courts must look first to the words chosen by Congress in the MDA's preemption provision:

> [N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device under this chapter.

21 U.S.C. § 360k(a).

As this language makes clear, the MDA does not preempt all state-imposed forms of liability simply because they relate in some manner to the safety and effectiveness of a device subject to the MDA, as the court of appeals held. State device requirements are preempted only if they are "different from, or in addition to" pre-existing federal requirements that concern a device's safety and effectiveness. Thus, petitioner's claims, based on the Stableflex's defective design, the manufacturer's failure to warn, and breach of implied warranties, may be preempted under § 360k(a) only if there are federal requirements imposed upon manufacturers of IOLs regarding those subject matters. If, for instance, there were specific federal warnings that each purchaser or user of an IOL had to be given, as there are for tampons, *see* 21 C.F.R. § 801.430, then it might be argued that any state-imposed duty to warn over and above such warnings would be preempted. *See Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 & n.23 (5th Cir. 1989). But here there are no such warnings, nor are there substantive IOL requirements of any kind. *See* 5a ("the appropriate [IOL] regulations of safety and effectiveness are procedural rather than substantive ones"). If this view of § 360k(a) is correct, there is no preemption because there are no FDA requirements dealing with any of those subjects.

The Seventh Circuit held that, because the Stableflex had obtained approval under the FDA's Investigational Exemptions for IOLs, 21 C.F.R. Part 813, *any* claim concerning the safety or effectiveness of an IOL against a manufacturer who obtained such an approval was preempted (7a). In doing so, the court relied on the purported comprehensiveness of these regulations (2a) and the importance of encouraging the marketing of investigational devices (6a), but made little attempt to square its ruling with the MDA's preemption provision and the FDA regulations promulgated thereunder. The court held that, simply because those regulations specify procedures for determining whether a particular investigational device is "safe and effective," they "are requirements relating to safety and effectiveness [under § 360k(a)] and they can have preemptive effect" (5a).

1. Petitioner's view of MDA preemption is precisely the one taken by the FDA in regulations which define what types of state and local authority are and are not preempted under 21 U.S.C. § 360k(a):

> State or local requirements are preempted *only where the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act*, thereby making any existing state or local requirement different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(emphasis added).

In promulgating these regulations, FDA explained why the preemptive effect of § 360k(a) must be interpreted narrowly. The Agency looked first to the words chosen by Congress, discussing the language dictating that there be a federal *requirement*, with respect to *a device*, and found that device-specific federal rules must first be in place before preemption can occur. 43 Fed. Reg. 18,661, 18,662 (May 2, 1978)(highlighting italicized statutory language). The FDA further explained:

> Thus, from a plain reading of section 521 of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. ... [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling ..., which occurred when the new FDA hearing aid regulations took effect... . [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution.

Id.

This insistence upon device-specific FDA requirements for the same subject matter regulated by the state -- what the FDA

refers to as the need for "specific counterpart" requirements -- is found throughout the FDA's regulations. For instance, the MDA does not preempt State or local registration or certification schemes for medical professionals simply because they "administer, dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). If, however, the FDA exercises its authority under the MDA to restrict the use of certain devices to particular health professionals, *see* 21 U.S.C. §§ 360j(e),(g), then the federal requirements control, but only to the extent that they actually conflict with state and local regulations. 21 C.F.R. § 808.1(d)(3). Similarly, states and localities may maintain general enforcement activities, such as factory inspections and record keeping rules, unless the FDA issues rules which conflict with such activities. *Id.* at § 808.1(d)(6)(i); *see also id.* at § 808.1(d)(6)(ii)(states and localities may prohibit the manufacture of adulterated or mislabeled devices, unless the FDA has established a specific labelling requirement for a specific device which is in conflict with the state or local requirement).

2. The weight of the case law also rejects the Seventh Circuit's approach -- that the existence of procedural mechanisms for the approval or disapproval of a device standing alone may have preemptive effect. Rather, the cases support the FDA's view that the scope of MDA preemption is narrow and occurs only where the FDA has issued device-specific regulations in the precise area in which the state or locality is attempting to regulate.

In *Moore v. Kimberly-Clark Corporation*, 867 F.2d 243, *supra*, the Fifth Circuit considered a tampon manufacturer's argument that the claims of a toxic shock syndrome ("TSS") victim were preempted both by the MDA itself and by FDA regulations directing tampon manufacturers to place detailed and specific warnings on tampon packages and package inserts. *See* 21 C.F.R. § 801.430. The plaintiff claimed that her TSS was attributable to the manufacturer's breach of the duty to warn and the improper design, composition, and construction of the tampon. The court recognized the FDA's authority to comprehensively regulate tampons, *Moore*, 867 F.2d at 244-45, but held that, because "the only federal requirements regarding tampons are those which prescribe certain labeling and warning statements," the plaintiff's state law claims concerning improper design and manufacture of

the tampon were not preempted. *Id.* at 246. The court relied heavily on the FDA's regulations narrowly defining the scope of preemption, *id.* at 244, 245, 247, and the belief that, to infer preemption because of the mere potential for comprehensive regulation of a field, "'would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.'" *Id.* at 245 (*quoting Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 717 (1985)).[2]

Precedent concerning hearing aids -- a subject of early FDA regulation under the MDA -- is also at odds with the Seventh Circuit's approach. In *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981), the court held that a Florida law concerning the sale of hearing aids was not preempted, even though the FDA had the power to regulate in that same area and had in fact issued certain requirements with respect to hearing aids. The court held, for instance, that 21 C.F.R. § 801.420(c), which requires sellers of hearing aids to provide information to prospective purchasers to promote consumer safety and improve the quality of the hearing aid, did not preempt Florida's requirement that sellers provide each purchaser with certain consumer information (*e.g.*, seller's business address, serial number of hearing aid, whether the

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[2] The Seventh Circuit apparently disagreed with *Moore*, indicating that *Moore* supported petitioner's argument (4a), and then explaining why, in its opinion, that argument was flawed. The conclusion reached in *Moore* -- that the FDA's tampon labeling requirements only preempt state duty to warn claims, but leave other claims unaffected -- has been followed by many courts. *E.g.*, *Bejarano v. Int'l Playtex, Inc.*, 750 F. Supp. 443, 446 (D. Idaho 1990); *Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164, 169 (W.D. Mich. 1990); *Rinehart v. Int'l Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988). A few courts have found broader preemption under the MDA. *See Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13 (D. Conn. 1989)(duty to warn claims for *all* prescription devices marketed after passage of MDA preempted pursuant to general labelling regulations); *Lavetter v. Int'l Playtex, Inc.*, 706 F. Supp. 722, 723 (D. Ariz. 1988)(preempting entire case, but unclear whether plaintiff made claims other than duty to warn); *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982)(preempting state law claim for warning to users of Dalkon Shield on ground that federal interest in medical devices is "dominant" and "pervasive," without citation or analysis of statutory or regulatory provisions on preemption). We note that the FDA rejected the broad preemption holding in *National Women's Health* in an advisory opinion (*see* 18a-19a).

hearing aid was new, used or rebuilt, where consumer complaints could be filed, etc.). *Smith*, 651 F.2d at 1024-25. Contrasting the FDA's effort to protect the safety of the user with Florida's efforts to safeguard consumers' rights after purchase, the court found "that the Florida statute does not relate 'to a matter included in a federal requirement applicable to a device'" and, therefore, was not preempted by the federal regulation. *Id.* at 1025. Similarly, the court affirmed Florida's authority to require a disclaimer concerning a hearing aid's inability to restore hearing loss on both the packaging containing the hearing aid and the customer's itemized receipt, even though there existed an FDA requirement that was satisfied if the disclaimer appeared in a brochure accompanying the hearing aid. Conceding that it was a closer question, Judge Hatchett concluded that, because the federal regulation dealt with an informational brochure, not packaging, there existed no federal regulatory requirement which could be said to preempt Florida law. *Id.*

In *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978), the New Jersey Supreme Court considered numerous state regulations designed to protect hearing aid consumers, similar to, but in some ways more comprehensive than, those at issue in *Pingree*. These proscriptions included banning the use of certain misleading professional titles, requiring price lists for hearing aids, barring non-consensual home visits by sellers, setting price guidelines, and the like. The court began its preemption discussion by recognizing the circumspection which must attend claims of federal preemption in areas of traditional state concern, such as public health, 384 A.2d at 808, and then reviewed the FDA's proposed regulations concerning the MDA's preemptive effect, now codified at 21 C.F.R. § 808.1. In light of the "fundamental maxim that the opinion as to the construction of a regulatory statute of the expert administrative agency charged with the enforcement of that statute is entitled to great weight," 384 A.2d at 810, the court chose to "follow the FDA's reasonable interpretation" of § 360k(a) because there "are no 'compelling indications that it is wrong.'" *Id.* (*quoting Red Lion Broadcasting*

Co. v. F.C.C., 395 U.S. 367, 381 (1969)).[3]

The approach taken in the majority of the tampon and hearing aid cases is directly at odds with the decision below. The court of appeals here looked to what it believed to be the general policy behind the investigational device regulations (5a-6a), not to "special features warranting preemption." *Hillsborough County*, 471 U.S. at 719. That approach simply cannot be squared with cases such as *Moore*, *supra*, under which claims for defective design of an investigational device would not be preempted simply by the existence of regulations allowing a manufacturer to apply for investigational approval.[4]

3. The decision below is also inconsistent with the narrow approach to preemption taken by this Court, most recently in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), which was decided a month after rehearing was denied below. In *Cipollone*, the Court considered the preemptive effect of § 5(b) of the Public Health Cigarette Smoking Act of 1969, on a variety of damage claims raised by a cigarette user who had died from using the defendant's product. Section 5(b) provided that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 2617. Section 4 of the Act mandated that a specific warning be placed on all cigarette packaging and advertising. *Id.* at 2616.

This Court rejected the manufacturer's argument that all of

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[3] Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984), the FDA's final regulations would be entitled to even greater respect. *See Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985)(applying *Chevron* to defer to FDA's position narrowly construing preemption of state and local regulation of blood donation centers, despite compreshensive federal regulation).

[4] *See also, e.g.*, 45 Fed. Reg. 67,321, 67,323 (October 10, 1980)(states may require premarket approval of a specific device, even after passage of MDA, until FDA requires such approval for that device).

Cipollone's damage claims were preempted, and instead analyzed each cause of action in light of § 5(b)'s language and purposes. Because Cipollone's duty to warn claims would create state-imposed tort liability on the basis of a failure to give a warning over and above the specific warnings required by Congress, those claims were preempted. *Id.* at 2621. But other claims -- fraudulent misrepresentation, conspiracy to misrepresent or conceal facts, and breach of warranty -- were not preempted, because, while they dealt with "smoking and health" in some sense, they were grounded on either a general tort duty not to deceive or on a contractual relationship between the parties. *Id.* at 2623-24 & n.27.

Under *Cipollone*, then, the duty to warn claims were preempted precisely because mandatory federal warnings were the centerpiece of a federal law and of its preemption provision; in *Moore* and the other tampon cases, such claims were preempted for the essentially same reason -- that mandatory warnings were the subject of a specific federal requirement. But also for the same reason, the tampon cases, consistent with *Cipollone*, generally hold that design defect claims are *not* preempted, because tampon design is *not* the subject of a federal requirement. Put another way, if the FDA had promulgated mandatory labeling for IOLs, as it has for tampons and hearing aids, then *Moore* and *Cipollone* might require preemption of petitioner's duty to warn claim, but no others. However, since there are *no* federal labeling requirements or design specifications, the preemption of petitioner's duty to warn and design defect claims cannot be squared with the approach taken in *Cipollone*.

Cipollone's holding on the breach of warranty claim is particularly noteworthy. Just as the "requirements" of Cipollone's UCC breach of warranty claim were not imposed under state law, but were based on what the manufacturer promised, *id.* at 2622, so too here, where petitioner has alleged that respondent has breached two types of warranties enforceable under the Illinois UCC, those claims are not preempted. Amd. Compl. ¶¶ 24-26 (breach of implied warranty of merchantability and of fitness for particular purpose). Indeed, the FDA has made absolutely clear that 21 U.S.C. § 360k(a)

> does not preempt State or local requirements of general applicability where the purpose of the requirement relates ... to other products in addition to devices (e.g., requirements such as general electrical codes, and *the Uniform Commercial Code (warranty of fitness)*) ... .

21 C.F.R. § 808.1(d)(1)(emphasis added).

* * *

In summary, the Seventh Circuit analyzed petitioner's claims without focusing on the relevant statutory and regulatory provisions (it did not even mention petitioner's warranty claims, or the FDA regulation preserving those claims), but instead found that they are preempted simply because they deal with "safety and effectiveness" of a device (5a). The same type of argument was made in *Cipollone*, and the Court held that all of the plaintiff's claims there were not preempted simply because they generally concerned "smoking and health." 112 S. Ct. at 2624 n.27. The court of appeals' decision thus "conflicts both with the background presumption against preemption and with ... Congress'... intent to preserve the 'police regulations' of the States" under the MDA, *id.*, unless there are specific federal requirements that conflict head-on with State law.

B. The Court of Appeals Erred in Assuming That the MDA Preempts Damage Claims.

The Seventh Circuit's decision also warrants this Court's consideration because, in finding that petitioner's claims were preempted in their entirety, Judge Posner necessarily (and, we believe, incorrectly) assumed that Congress intended to preempt common law damage claims such as those alleged here. While we acknowledge that the courts have expressed differing views on this question -- generally finding preemption of at least *some* damage claims under the MDA -- the preemption of state-law damage claims ascribes to Congress an intent that cannot be squared with the statutory language, the legislative history, or the FDA's

regulations.[5]

In *Cipollone*, this Court held that, under the Smoking Act of 1969, a "requirement ... based on smoking and health ... imposed under state law" was a reference to a common law damage recovery, as well as positive statutory and regulatory law. 112 S. Ct. at 2620-21. It did so on the basis of various statutory indicia, including legislative history and a change made from a prior version of the Act, all of which pointed in the direction of preemption of some damage claims. *Id.* As always, the focus was Congressional intent as evidenced by the relevant statutory materials. *Id.*

Thus, while we do not dispute that a reference to "a requirement ... under state law," may, in some circumstances, include common law claims, review of the specific provision at issue here -- 21 U.S.C. § 360k -- suggests that damage claims are not preempted. First, § 360k(a) does *not* refer to "State law;" it says that "no State or political subdivision of a State may establish or continue in effect" certain device "requirements." We do not doubt that a "requirement" under § 360k(a) may include a judicial order (such as the enforcement or the interpretation of a state law or regulation concerning devices), *see* 21 C.F.R. § 808.1(b); however, it strains ordinary English usage to the breaking point to say that a jury award to a tort plaintiff such as petitioner constitutes a "State ... establish[ing] or continu[ing] in effect" a device requirement.

Read most naturally, § 360k(a) concerns state and local statutes, ordinances, and regulations that impose affirmative requirements on device manufacturers, such as those at issue in *New Jersey Guild*, *supra*. Not surprisingly, neither the legislative history, H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 4, 45-46 (1976), nor the extensive regulatory history concerning both the scope of MDA preemption in general and the FDA's regulatory decisions

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[5] Petitioner recognizes that this argument is broader than the one made in the prior section and would permit even the duty to warn claims found to be preempted in *Moore* and the other tampon cases to go forward.

on whether specific state requirements are preempted, even suggests, let alone makes explicit, that common law remedies are preempted. Rather, the legislative history and the FDA's regulatory comments are replete with references to the preemption provision's application to the actions of state and local legislative and regulatory bodies.[6]

Indeed, the FDA has made clear that tort-like remedies are not preempted. "State or local requirements of general applicability" that "relate[] to other products in addition to devices ... or to unfair trade practices in which the requirements are not limited to devices" are not preempted. 21 C.F.R. § 808.1(d)(1). Damage claims would not be preempted because they "generally pertain ... to persons who manufacture or distribute devices ..., and [do] not [pertain] directly to devices." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978). "In order for a State provision to be a requirement with respect to a device within the meaning of section 521 of the act -- and thereby a candidate for preemption -- it must relate to the device itself." *Id.* This is precisely why the FDA, in an advisory opinion, rejected the preemption holding in *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982), where the plaintiff had sought a warning to all users of the Dalkon Shield intrauterine device *under Massachusetts tort law*. The FDA stated that "the act preempts only State and local requirements that directly and specifically relate to devices" (18a). Thus, "*[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to device' within the meaning of section 521(a) of the act*" (19a)(emphasis added).

Moreover, the existence of 21 U.S.C. § 360k(*b*) -- a provision not mentioned by the court of appeals -- further undermines the contention that the section is applicable to damage claims. Subsection (b) allows States or their political subdivisions to apply to the FDA for exemptions, so that they can maintain requirements

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[6] H.R. Rep. No. 94-853, *supra* at 4, 45-46 (1976); 45 Fed. Reg. at 67,321-67,324 (Oct. 10, 1980); 43 Fed. Reg. at 18,662-18,664 (May 2, 1978); *see also Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989)(relying on legislative history).

that are otherwise preempted under certain circumstances. Subsection (b)'s language is parallel to that of subsection (a), and, thus, it allows applications only by a "State or a political subdivision" to exempt "a requirement" "applicable to a device intended for human use." 21 U.S.C. § 360k(b). Thus, subsection (b) does *not* apply, and could not sensibly be read to apply, to the establishment of common law duties or jury awards. *See also* 21 C.F.R. §§ 808.20, 808.25 (making clear that device "requirements" for which exemption is sought under § 360k(b) refer only to positive enactments of state and local governments). To suggest that subsection (a), however, *does* apply to damage awards, would impose upon § 360(k) an awkward and illogical asymmetry that has no basis in the statute or the FDA's regulations.

We recognize that most courts, all of them in the tampon cases, *see Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1062 n.2 (D. Minn. 1989)(collecting cases), have held that subsection (a) can preempt some common law claims, but many of them simply assumed that conclusion, and *none* has considered the effect of subsection (b). The one court to have considered subsection (b) in a damage action held that "[t]he plain language of § 360k indicates that Congress intended to preempt state or local legislation and administrative regulations governing devices, not state tort law." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989)(alternative holding). The court explained that, "if the term 'requirement' were interpreted so as to include tort law, the exemption provision [of 21 U.S.C. § 360k(b)] would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of an IUD tort plaintiff?"[7]

In our view, the MDA does not contain the "clear and manifest" Congressional purpose necessary to preempt any common

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[7] *Accord Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298 (D. Minn. 1989)(dicta); *cf. New Jersey Guild*, 384 A.2d at 813-14 (existence of § 360k(b) strong evidence of narrow preemptive scope of § 360k(a)). In addition, at least two district courts have held in unreported decisions that § 360k(a) does *not* preempt any common law claims. *Discussed in Berger v. Personal Products, Inc.*, 797 P.2d 1148, 1151 & n.16 (Wash. 1990).

law tort liability. *See Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2482, 2485 (1991); *Cipollone*, 112 S. Ct. at 2626 & n.1 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). In any event, the Seventh Circuit's decision that 21 U.S.C. § 360k(a) expressly ousts state law-based jury awards is sufficiently problematic to warrant review.

C. There is a Split in Authority Over the FDA's Savings Clause for Liability Actions Pertaining to Investigational Devices.

The final basis for review is the conflict between the decision below and *Mitchell v. IOLAB Corp.*, 700 F. Supp. 877 (E.D. La. 1988), over the meaning of 21 C.F.R. § 50.20. That provision concerns the type of informed consent that must be given to patients who use investigational devices marketed under the MDA, and is incorporated by reference in the IOL regulations upon which the court of appeals relied in finding preemption. *See, e.g.*, 21 C.F.R. § 813.5(c)(4). Section 50.20 provides in relevant part:

> No informed consent [to the use by a patient of an investigatory medical device], whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Mitchell held that § 50.20 "clearly preserves the subject's legal rights," 700 F. Supp. at 879, thus allowing the plaintiff's state law claim against the sponsor (*i.e.*, manufacturer) for defective design of an investigational IOL to proceed. *Id.* at 878. The court reasoned that, by safeguarding a patient's state law claims against device manufacturers, § 50.20 "effectively ... establishes that state tort law is neither '... different from, or in addition to, any requirement applicable under this Act to the device ... which relates to the safety and effectiveness of the device ...'." *Mitchell*, 700 F. Supp. at 879 (*quoting* 21 U.S.C. § 360k(a)).

Here, on the other hand, the court of appeals held that § 50.20 simply preserves claims that are not otherwise preempted (7a). In Judge Posner's view, § 50.20 means only that § 360k(a) does not preempt claims for negligent implantation or contamination of IOLs, principally against doctors and hospitals (*id.*)(citing cases). In our view, this position suffers from two related problems. First, § 50.20 specifically applies to manufacturers of devices, not only doctors and hospitals who use those devices. Thus, § 50.20's requirement that device manufacturers not be allowed to demand the release of a patient's legal rights or disclaim their liability for negligence would be rendered virtually meaningless.

Second, the court of appeals' decision leaves petitioner with no legal remedy for injuries sustained at the hands of a manufacturer, no matter how severe the injury or willful or malicious the manufacturer's failure to warn unsuspecting users or to properly design the device. The court of appeals' response to this is that petitioner assumed the risk of using an investigational device, and that it is "economic substance" (6a), not the availability of a legal remedy, that should guide the preemption analysis.

While assumption of the risk may be a factor in determining whether and to what extent Illinois law provides a remedy, it has nothing to do with whether § 360k(a) *expressly* preempts all damage claims against respondent. To the extent that assumption of risk might be considered at all, it is not an express preemption argument, but rather a suggestion that the MDA's scheme of investigational device exemptions, under which a patient consents to the use of the device, *impliedly* preempts any state-law damage claim. But such an argument necessarily fails, because, when Congress has enacted an express preemption provision, as it has done here, "matters beyond [its] reach are not pre-empted." *Cipollone*, 112 S. Ct. at 2618; *see also id.* at 2625 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part)("We resort to principles of implied preemption ... only when Congress has been silent with respect to preemption"); *New Jersey Guild*, 384 A.2d at 813-14.

Similarly, the court of appeals' reliance on what it termed

"economic substance" -- that preemption of tort claims is a good thing because it will bring more investigational devices to market -- may or may not be correct, but it is irrelevant to the question at issue here -- Congress' intent in enacting § 360k. In any event, the court of appeals' cost/benefit analysis has no basis in this Court's Supremacy Clause jurisprudence, which has been loathe to preempt state damage claims, where, as here, "Congress [has] fail[ed] to provide any federal remedy for persons injured by" respondent. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). As the foregoing discussion indicates, "Congress would [not], without comment, remove all means of judicial recourse for those injured by [the] illegal conduct" of device manufacturers. *Id.*; *accord English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Callan*, 709 F. Supp. at 667.

Thus, at a minimum, § 50.20 reenforces the FDA's view that the scope of MDA preemption is narrow, and that preemption does not apply where there are no substantive federal IOL requirements that specifically parallel petitioner's state law claims. Moreover, § 50.20 is fully consistent with this Court's view that injured consumers should not be divested of all damage remedies provided by state law, unless Congress has made absolutely clear that such a result is desired. This Court should grant review to resolve the split of authority on the meaning of § 50.20, and, more fundamentally, to give guidance to the lower courts on the scope of MDA preemption.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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Attorneys for Petitioner

August 17, 1992

In the
United States Court of Appeals
For the Seventh Circuit

No. 91-1544
ALBERT SLATER,

Plaintiff-Appellant,

v.

OPTICAL RADIATION CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division
No. 88 C 9076-**Paul E. Plunkett**, *Judge*.

ARGUED DECEMBER 2, 1991-DECIDED APRIL 22, 1992

Before POSNER and MANION, *Circuit Judges*, and FAIRCHILD, *Senior Circuit Judge*.

POSNER, *Circuit Judge*. The district judge dismissed this diversity personal-injury suit on the pleadings, on the ground that it was preempted by an investigational-device exemption issued by the Food and Drug Administration under the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301 *et seq.* 756 F. Supp. 370 (N.D. Ill. 1991). He thus disagreed with *Mitchell v. IOLAB Corp.*, 700 F. Supp. 877 (E.D. La. 1988), the only other case concerning the preemptive force of an exemption for an investigational device--which makes ours a case of first impression at the appellate level.

The Amendments gave the FDA comprehensive regulatory authority over medical devices for the first time. H. R. Rep. No.

853, 94th Cong., 2d Sess. 1, 6-13 (1976). Among other things, the Amendments authorize the agency to promulgate implementing regulations, 21 U.S.C. § 371(a), and forbid states to subject a medical device to "any requirement (1) which is different from, or in addition to, any requirement applicable under the [Amendments] to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under" the Amendments. § 360k(a). In regulations the validity of which neither party questions, the FDA has declared that preemption, though equally applicable whether the state is acting "by statute, ordinance, regulation, or court decision," is limited to cases in which the FDA "has established specific counterpart regulations [to the challenged state requirements] or there are other specific requirements applicable to a particular device under" the federal act. 21 C.F.R. §§ 808.1(b), (d).

In the year following the enactment of the Medical Device Amendments, the FDA issued "Investigational Device Exemption Regulations" for intraocular lenses. 21 C.F.R. pt. 813. Such exemptions, which the Amendments expressly authorize the FDA to grant upon application, 21 U.S.C. § 360j(g), are intended to encourage innovation by exempting promising experimental devices from the usual requirement of establishing the safety and efficacy of a medical device before it can be sold. Cf. H.R. Rep. No. 853, *supra*, at 12, 42. The regulatory exemption is not total. (See *United States v. An Article of Device*, 731 F.2d 1253, 1258 (7th Cir. 1984), and with specific reference to the exemption for intraocular lenses *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1283 (D.C. Cir. 1983), and *Surgidev Corp. v. Eye Technology, Inc.*, 648 F. Supp. 661, 684 (D. Minn. 1986), aff'd, 828 F.2d 452 (8th Cir. 1987).) A detailed explanation is required, describing the device and setting forth a plan for studying its use in human subjects ("clinical investigation") during the experimental period. 21 C.F.R. § 813.20. The application must be reviewed by an institutional review committee as well as by the FDA before it can be approved. §§ 813.20, 813.30. After approval, the committee has a duty to monitor the clinical investigation. § 813.65. Congress expected the FDA to grant an investigational-device exemption for intraocular lenses; we know this because the Medical Device

Amendments contain a specific provision intended to require the FDA to make intraocular lenses "reasonably available to physicians meeting appropriate qualifications" if an investigational exemption is granted. 21 U.S.C. § 360j(*l*)(3)(D)(iii); H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 63 (1976); *American Society of Cataract & Refractive Surgery v. Sullivan*, 772 F. Supp. 666, 673 (D.D.C. 1991).

Intraocular lenses are plastic lenses implanted in the eyes of persons who have undergone surgery for the removal of cataracts. Richard B.S. Packard & Fiona C. Kinnear, *Manual of Cataract and Intraocular Lens Surgery* (1991). The removal of a cataract destroys the (natural) lens on which the cataract has formed, and restoration of focused vision requires either special cataract glasses, a contact lens, or an intraocular lens (behind the cornea). Alfred Mamelok, "Cataract," in 3 Roscoe N. Gray & Louise J. Gordy, *Attorneys' Textbook of Medicine* ¶¶ 56.45, at pp. 56-50 to 56-52 (3d ed. 1991). Now standard treatment for cataract patients, intraocular lenses were experimental back in the 1970s when the investigational-device exemption for such lenses was issued, and for some years afterward.

Optical Radiation Corporation, the defendant in this case, manufactured an intraocular lens called "Stableflex." This was an anterior-chamber intraocular lens (that is, it was installed in the anterior chamber of the eye, which is a space between the cornea and the iris), a type of lens manufactured by several other companies as well. All of these lenses, as well as intraocular lenses of different design, received investigational-device exemptions. In 1984, Slater, the plaintiff in this case, had a cataract removed and a Stableflex implanted in the eye. Before the operation he signed a form in which he consented to participate in the clinical investigation of this experimental device. After the operation, according to the allegations of the complaint, the vision in Slater's left eye deteriorated, he experienced continuous pain, the eye became infected, and eventually the implant had to be removed, leaving him with permanent damage to the eye (beyond the damage done by the cataract itself). The surgeon who performed the removal found the lens "cocooned" in the eye--which he thought due to the fact that the lens had an awkward design--and

therefore difficult to remove. This model of the Stableflex was later withdrawn from the market. David J. Apple *et al.*, *Intraocular Lenses: Evolution, Designs, Complications, and Pathology* 88 (1989).

The suit is for the injury to Slater's eye allegedly caused by the implantation and removal of the lens. The complaint alleges inadequate clinical testing, defective design of the intraocular lens, and failure to warn the public of the lens's dangers. The district judge dismissed the suit on the ground that the plaintiff was seeking to impose in the name of Illinois tort law requirements relating to safety or effectiveness that were different from the requirements imposed by the FDA's regulations governing the experimental use of intraocular lenses.

The plaintiff's counsel wisely conceded at argument that insofar as the complaint might be construed to allege that Illinois tort law required the defendant to do more or different clinical testing of Stableflex than required by the FDA's regulations governing the investigational exemption for intraocular lenses, the suit is indeed preempted; for it would then be unquestionably a matter of imposing in the name of state law a different requirement relating to safety and effectiveness from that imposed by federal law. If the FDA in a valid regulation under the Medical Devices Amendments requires X, and X relates to safety or effectiveness, a state cannot, whether though statute, regulation, or common law decision, require non-X, or X + Y.

But the plaintiff's real gripe is not inadequate testing; it is defective design. Not only is the design of the Stableflex said to be defective, but there is a suggestion that the entire concept of an anterior-chamber lens is unsound and we are told that lawsuits are pending against other manufacturers of such lenses as well. The FDA's regulations impose no requirements concerning the design of intraocular lenses. Therefore, the plaintiff argues, there is no preemption of state products liability law relating to design defects. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989). He adds that if he has no damages remedy under state law, he has no damages remedy, period, as there is no federal damages remedy that he might invoke.

The argument assumes that the only federal requirement that might relate to the safety or effectiveness of the design of a medical device would be an actual specification of that design. The preemption provision does not say this, and so cramped an interpretation would cripple the exemption for investigational devices. The FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective. *Public Citizen Health Research Group v. FDA*, *supra*, 704 F.2d at 1283. In the experimental phase the appropriate regulations of safety and effectiveness are procedural rather than substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect.

Of course the FDA will not grant an investigational-device exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of its being used on human beings. Although that belief is different from a certification that the design of the device is safe and effective, it is a certification that the design is sufficiently safe and effective to allow experimental use on human beings. The theory underlying the complaint is that the design of the Stableflex was not sufficiently safe and effective to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided, whether rightly or wrongly, but pursuant to regulations the validity of which the plaintiff does not question, that Stableflex could be sold, subject only to requirements, procedural in character and, so far as appears, fully complied with, designed to assure that this experimental distribution was in fact a worthwhile experiment. The plaintiff wishes in the name of state tort law to impose additional requirements--namely that Stableflex have had design characteristics that it lacked--and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments.

It would be a mistake to conclude that preemption in these circumstances leaves the consuming public remediless, at least if we have concern for economic substance rather than legal formality and do not suppose that the only "remedies" (preventives, protections, correctives) are those that the law provides. The consent form that Mr. Slater signed informed him that he had a choice of treatments, one of which was experimental; he chose the experimental. The experimental procedure was riskier because, by definition, there was limited experience with it. Provided the risks, including any loss of tort remedies, were adequately explained to Slater, he cannot complain that the risks materialized. We add that if experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.

The scope of the preemption, moreover, is limited. It is limited to efforts by states to impose sanctions for compliance with federal regulations relating to the safety or efficacy of the experimental lenses. It does not affect cases charging negligence in the implantation or removal of a lens, or complaining of contamination of the lens by bacteria or fungi or of failure to obtain the patient's informed consent to the procedure. *Kus v. Sherman Hospital*, 204 Ill. App. 3d 66, 561 N.E.2d 381 (1990) (implantation of lens of which the FDA had withdrawn its approval); *Green v. Wedowee Hospital*, 584 So. 2d 1309 (Ala. 1991) (implantation in wrong eye); *Hudson v. Taieff*, 546 So. 2d 359 (Miss. 1989) (unspecified negligence in implantation); *Kershaw v. Reichert*, 445 N.W.2d 16 (N.D. 1989) (lack of informed consent); *United States v. Torigian Laboratories, Inc.*, 577 F. Supp. 1514 (E.D.N.Y.), affirmed without opinion, 751 F.2d 373 (2d Cir. 1984) (unsterilized lens); *In re Luminex International, Inc. Products Liability Litigation*, 434 F. Supp. 668 (Judicial Panel on Multidistrict Litigation 1977) (per curiam) (lens contaminated by fungus). It is not the sort of blanket preemption that we find in ERISA, which supersedes "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987); *Pohl v. National Benefits Consultants, Inc.*, No. 91-1809, slip op. at 2-3 (7th Cir. Jan. 31, 1992). The limited scope of the preemption

explains the prohibition incorporated by reference in the investigational-device exemption for intraocular lenses, 21 C.F.R. 813.1 *et seq.*, against the inclusion of "any exculpatory language" in consent forms. § 50.20. The prohibition preserves the patient's common law rights outside of the limited scope of the preemption provision. It does not, as the district court held in the *Mitchell* case, 700 F. Supp. at 878-79, repeal the preemption provision itself.

Even within the scope of the preemption there is an important qualification. The risks of the experimental procedure must be adequately explained to the patient. 21 U.S.C. 360j(g)(3)(D); 21 C.F.R. § 813.66(a)(6). The tort law of medical battery, which is violated when an operation is performed without the patient's informed consent, is not preempted. Slater's complaint alleges that Optical Radiation Corporation failed to warn the public of the dangers of the Stableflex lens. We are not sure what he is driving at. The lens was not marketed to the public. It was an experimental device provided to patients together with such warnings as might be necessary to elicit informed consent to the implantation of it. We do not understand Slater to be arguing that he did not give his informed consent to the implantation. The consent form that he signed adequately discloses the medical risks of the procedure. True, it does not indicate that by signing the form he will be giving up any legal rights. It says, "I understand that in the event of physical injury resulting from this clinical study, there is no compensation available from Hinsdale Sanitarium and Hospital [where the cataract operation and lens implantation were performed] for such injury." This could be taken to imply that of course the signator is not waiving any right to seek compensation from the manufacturer of the lens for having designed or manufactured it defectively. But Slater has made nothing of this, either in our court or in the district court. His complaint, variously expressed, is that the Stableflex was too dangerous even for experimental use. That complaint is barred by the preemption provision of the Medical Devices Amendment.

AFFIRMED.

A true Copy:
Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

Albert SLATER, Plaintiff,

v.

OPTICAL RADIATION CORPORATION,

Defendant

No. 88 C 9076.

United States District Court, N.D. Illinois, E.D.

Jan. 31, 1991.

MEMORANDUM OPINION AND ORDER

PLUNKETT, District Judge.

Plaintiff Albert Slater ("Slater") has filed an amended complaint ("complaint") against defendant Optical Radiation Corporation ("ORC") for injuries allegedly sustained as a result of the implantation of a device manufactured by ORC, known as the Stableflex anterior intraocular lens. Plaintiff's complaint sounds in negligence, strict liability, and breach of an implied warranty and seeks punitive damages. Before us today is (1) ORC's motion to dismiss all counts of the complaint on the ground that Slater's claims are preempted by federal law, and (2) ORC's motion for summary judgment[1] on Count Four, the count which seeks an award of punitive damages. For the reasons set out below, we grant ORC's motion to dismiss all counts of the complaint on the ground that plaintiff's claims are expressly preempted by federal law. We do not reach ORC's motion for summary judgment on Count Four.

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[1] ORC styles both of its motions as motions to dismiss. It is clear, however, that this second motion is really a motion for summary judgment in that it asks us to look at materials outside the pleadings to determine whether or not the facts of this case support an award of punitive damages. *See* Fed.R.Civ.P. 12(b) (last sentence).

Facts

Because we are only ruling on ORC's motion to dismiss, for today's purposes we assume all facts alleged in the complaint are true along with all reasonable inferences therefrom in the light most favorable to Slater, the plaintiff. *Powe v. City of Chicago*, 664 F.2d 639, 642 (7th Cir.1981). On July 19, 1984, Slater was admitted into the Hinsdale Hospital in Hinsdale, Illinois to have a cataract removed from his left eye and to have an implant placed therein. The surgery was performed by Dr. David Whitsel, who is now deceased. Dr. Whitsel performed the extracapsular cataract extraction and inserted an anterior chamber intraocular lens in Slater's left eye. The lens was a Stableflex Model # UV-11-H, a product manufactured, designed, marketed, promoted, sold and distributed by ORC. At the time of Slater's lens implant, the Stableflex Model # UV-11-H intraocular lens was part of a clinical investigation conducted pursuant to 21 C.F.R. § 813 *et seq*.[2] (*See* discussion, *infra*).[3]

Over the next three years, Slater's left eye problems became worse. On January 8, 1986, Slater went to the Mayo Clinic in Rochester, Minnesota to receive treatment for his left eye. His left eye caused him great physical pain and had become infected. Slater was told that he was suffering from cestoid muscular edema. The doctors at the Mayo Clinic told him that there was no treatment available for his ailment, and told him to return in one year.

In January of 1987, Slater returned to the Mayo Clinic and was treated by two new doctors, Dr. R.R. Waller and Dr. Leo Maguire. Dr. Maguire recommended that the lens implant be removed because the pressure in Slater's left eye was dangerously

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[2] This fact is not disputed by the parties. To the extent that this is a fact obtained from materials outside the pleadings, we treat ORC's motion as a motion for summary judgment pursuant to Fed.R.Civ.P. 56.

[3] On June 25, 1984, prior to the implantation of the lens, Slater signed a consent form wherein he recognized that he was taking part in a clinical investigation monitored by the Food and Drug Administration. *See* footnote 2, *supra*.

low and because the tissue in his left eye was very soft. The operation to remove the lens implant was conducted on June 4, 1987.

On April 7, 1989, Slater filed the amended complaint in this action for injuries he sustained as a result of the insertion of the Stableflex intraocular lens manufactured by ORC. Count One alleges a cause of action for negligence. Specifically, Slater alleges that ORC was negligent in the performance or omission of seven acts:

1. Failed to engage in proper clinical testing in order to detect the effect of its Stableflex intraocular lens upon the human eye;

2. Distributed and sold its Stableflex intraocular lens in the market for implantation in the human eye knowing that it was not properly clinically tested and that it may cause damage to the human eye;

3. Failed to adequately warn the consuming public that its Stableflex intraocular lens had not been clinically tested for implantation in the human eye and that it could cause damage to the human eye;

4. Failed to inspect and discover that its Stableflex intraocular lens's design was defective and not fit for implantation in the human eye;

5. Failed to give adequate warnings as to the dangers of its Stableflex intraocular lens after its distribution and sale of the lens in July of 1984;

6. Knew or should have known that its Stableflex intraocular lens was designed improperly and was not fit for implantation in the human eye, and failed to warn the consuming public of its dangers; and

7. Was otherwise negligent in its responsibility as the manufacturer, designer and distributor of its Stableflex

> intraocular lens to take the necessary precautions that the lens was safe for implantation in the human eye.

(Compl. ¶¶ 17-19). Count Two alleges a cause of action for strict product liability. Specifically, Slater alleges that ORC manufactured, sold, and placed in the stream of commerce an unreasonably dangerous and defective product which was unsafe at the time it left ORC's control. (Compl. ¶¶ 20-23). Count Three alleges a cause of action for breach of the implied warranty that the Stableflex lens was of merchantable quality. Ill. Rev. Stat. ch. 26, ¶¶ 2-314, 2-315. (Compl. ¶¶ 24-26). Count Four alleges a cause of action for wilful and wanton conduct of the above acts and omissions and seeks punitive damages therefor. (Compl. ¶¶ 27-32).

Discussion

ORC moves to dismiss all counts of the complaint on the ground that Slater's claims are preempted by federal law. It is well established that under the Supremacy Clause of the United States Constitution, state laws that "interfere with, or are contrary to," federal law are invalid. U.S. Const., art. VI, cl. 2. Preemption can take one of three forms: (1) express preemption, where Congress passes a statute that by its express terms preempts state law; (2) implied preemption, where "federal legislation is 'sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation;'" *International Paper Co. v. Ouellette*, 479 U.S. 481, 107 S.Ct. 805, 811, 93 L.Ed.2d 883 (1987) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947)); and (3) actual preemption, where Congress speaks neither expressly nor impliedly of preemption, but state law is nevertheless preempted to the extent it actually conflicts with a-federal statute or rule. *International Paper*, 107 S.Ct. at 811. ORC argues that Slater's claims are both expressly and impliedly preempted.

We begin (and eventually end) with ORC's argument that

Slater's claims are expressly preempted.[4] In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301 *et seq.*, to protect the public health and safety and to bolster the Food and Drug Administration's regulatory powers. *See* 1976 U.S.Code Cong. & Admin.News (90 Stat.) 539. Congress delegated to the Food and Drug Administration ("FDA") the "authority to promulgate regulations for the efficient enforcement of this chapter...." 21 U.S.C. § 371(a). As part of the federal regulatory scheme, Congress enacted 21 U.S.C. § 360k(a)[5] which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and
> >
> > (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA].

Thereafter, the FDA promulgated regulations to enforce the FDCA. Specifically, the FDA promulgated 21 C.F.R. § 808.1(b) which states:

> Section 521(a) of the act [21 U.S.C. § 360k(a)] contains special provisions governing the regulation of devices by States and localities. That section proscribes a general rule that . . . no State or political subdivision of a State may establish or continue in effect any requirement with respect

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[4] The following discussion of the relevant statutes, regulations and legislative history is borrowed in large part from the Fifth Circuit's well-reasoned opinion in *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244-245 (5th Cir. 1989).

[5] Section 521(a) of the FDCA, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.

> to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*); which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(emphasis added). The FDA did not intend to preempt all state laws and regulations pertaining to "devices intended for human use," such as intraocular lenses.[6] This is made clear in 21 C.F.R. § 801.1(d) which provides that:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act...."

The result is that 21 U.S.C. § 360k(a), as interpreted by the FDA in 21 C.F.R. § 801.1, expressly preempts any state tort standard which would impose requirements on producers of medical devices which are "different from, or in addition to" the "specific counterpart regulations or . . . other specific requirements" promulgated by the FDA.

In November of 1977, the FDA issued Investigational Device Exemption ("IDE") Regulations for intraocular lenses pursuant to the FDCA. These regulations are found at 21 C.F.R. § 813 *et seq.* They establish rules for the investigational use of intraocular lenses as permitted by 21 U.S.C. § 360j(g),[7] which allows the FDA to exempt devices from the otherwise stated provisions of the FDCA for investigational use to determine their safety and effectiveness. The intraocular lens IDE regulations are quite extensive, and set forth in great detail the procedures and

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[6] Intraocular lenses are classified as Class III (Premarket approval) medical devises under the terms of the FDCA. *See* 21 U.S.C. § 360c, 21 C.F.R. § 813 *et seq.*

[7] Section 520(g) of the FDCA.

conditions under which intraocular lens manufacturers can be granted exemptions from the safety and effectiveness requirements of the FDCA.

We find that the Investigational Device Exemption Regulations for intraocular lenses expressly preempts state law claims *based on safety or effectiveness* of a particular intraocular lens where that lens has been granted an investigational device exemption by the FDA. The FDA made it clear that state regulations and requirements, including those imposed through court decisions imposing tort liability, are expressly preempted when the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the" FDCA. 21 C.F.R. § 801.1(d). In the case of intraocular lenses, the FDA has established such a specific requirement applicable to the lenses -- they can be exempt from the otherwise applicable requirements of the FDCA for safety and effectiveness.

It is undisputed that at the time of the implant of the ORC Stableflex lens into Slater's left eye, the Stableflex lens was the subject of a clinical investigation conducted pursuant to 21 C.F.R. § 813 *et seq.* Slater's claims in this case are all based upon the safety or effectiveness of the Stableflex lens. Count One alleges that ORC committed seven negligent acts, all of which relate to clinical testing (the subject of the IDE) or the safety or effectiveness of the Stableflex lens. Count Two alleges strict product liability based on the premise that the Stableflex lens was dangerous and defective -- a claim based on the safety or effectiveness of the lens. Count Three alleges a breach of the implied warranty that the lens was of merchantable quality, - again, a claim based on the safety or effectiveness of the lens. Finally, Count Four alleges that ORC committed the acts alleged in Counts One through Three wilfully, and wantonly, and seeks punitive damages. To the extent Count Four is derivative of Counts One through Three it is also based on the safety or effectiveness of the lens. The imposition of state tort requirements in this case would clearly be "different from, or in addition to" both the terms of the FDCA and the requirements of the IDE regulations promulgated by the FDA for safety or

effectiveness.[8] We therefore grant ORC's motion to dismiss on the ground that Slater's claims are expressly preempted by federal law.[9] Because we find Slater's claims to be expressly preempted, we do not reach the issues of implied or actual preemption.

Conclusion

For the reasons set out above, we grant defendant Optical Radiation Corporation's motion to dismiss the amended complaint on the ground that plaintiff Albert Slater's state law claims are expressly preempted by federal law.

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[8] Our ruling today is consistent with the court's ruling in *Mitchell v. IOLAB Corp.*, 700 F.Supp. 877, 878-79 (E.D. La. 1988), the only reported case applying the preemption laws to intraocular lenses under the FDCA and FDA regulations. That court described the applicable statutory and regulatory background of intraocular lenses. However, that court concluded that because the requirements for informed consent under Louisiana law are not "different from, or in addition to" the requirements under the FDCA and FDA regulation, the plaintiff's state law tort claims were not preempted. While the opinion in *Mitchell* is not clear, it appears that the state law tort claims were based on the requirements for informed consent under Louisiana law. The instant case is quite different in that Slater's state law tort claims are based directly on the safety or effectiveness of the Stableflex lenses.

[9] Both parties argue heavily from a series of cases applying the preemption doctrine to state law regulation of tampons. *See, e.g. Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Edmonson v. International Playtex, Inc.*, 678 F.Supp. 1571 (N.D. Ga. 1987); *LaVetter v. International Playtex, Inc.*, 706 F.Supp. 722 (D.Ariz. 1988). We find the analysis of those cases to be inapplicable here. There is no equivalent of the investigational Device Exemption Regulations of intraocular lenses for tampons. The Medical Device Amendments to the FDCA expressly preempts state tort claims based on tampon labeling and warning, but not design. The intraocular lens IDE regulations expressly preempt all aspects of intraocular lens safety and effectiveness.

United States Court of Appeals

For the Seventh Circuit

Chicago, Illinois 60604

May 20, 1992

Before

Hon. Richard A. Posner, Circuit Judge

Hon. Daniel A. Manion, Circuit Judge

Hon. Thomas E. Fairchild, Senior Circuit Judge

ALBERT SLATER, *Plaintiff-Appellant*,	)	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division. No. 88 C 9076 Paul E. Plunkett, *Judge*
No. 91-1544 v.	)	
OPTICAL RADIATION CORPORATION, *Defendant-Appellee*.	)	

ORDER

On May 6, 1992, plaintiff-appellant filed a petition for rehearing with suggestion for rehearing en banc. All of the judges on the original panel have voted to deny the petition, and none of the active judges has requested a vote on the suggestion for rehearing en banc. The petition is therefore DENIED.

Food and Drug Administration
Rockville MD 20857

March 8, 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You have requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. Under section 521(a) of the act, the act preempts only State of

local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to a device only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in *National Women's Health Network, et al. v. A.H. Robins Company, Inc.*, No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injunctive remedies. This advisory opinion does not address the merits of the application of such in any action filed by the network in the State of Massachusetts or any other State.

Sincerely yours,

/s/ Joseph P. Hile

Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]